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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/963,288	11/03/1997	GUNNAR NORSTEDT	10806-48	9881

7590 01/30/2003

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EXAMINER

FALK, ANNE MARIE

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/963,288

Applicant(s)

NORSTEDT ET AL.

Examiner

Anne-Marie Falk, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,7-11,15-17,19-21,23-32,34-36,39-42,44-50,52 and 53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,8-11,16,17,19-21,34-36,39-42,44-48,50 and 52 is/are allowed.
- 6) ☒ Claim(s) 5,7,15,23-32,49 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

The amendment filed October 28, 2002 (Paper No. 39) has been entered. Claims 1, 5, 8, 10, 15, 19, 23, 27, 30, and 44 have been amended.

Accordingly, Claims 1, 2, 5, 7-11, 15-17, 19-21, 23-32, 34-36, 39-42, 44-50, 52, and 53 remain pending in the instant application.

The following rejections are reiterated or newly applied and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous office action are hereby withdrawn.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/28/02 has been entered.

Specification

The amendment filed 10/28/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amendment at pages 2 to 3 changing 50 bp to 52 bp.

Applicant is required to cancel the new matter in the reply to this Office Action.

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No evidence is offered in support of the amendments to Examples 1, 2, and 3. While it is evident that the sequence set forth on page 2, paragraph 3, designated SEQ ID NO: 1, is 52 bp, not 50 bp, it is not evident that the element used in the experiments was the full 52 bp sequence. The specification as-filed consistently reports that a 50 bp element was used in the experiments presented in Examples 1-3. No evidence has been provided to support the amendment to the specification.

At page 7 of the response, Applicants point to the specification at page 2, paragraph 3 which discloses a sequence 52 bp in length, but refers to it as “the 50 bp SPI-GHRE.” However, it is unclear where the error occurred, whether it was with disclosing SEQ ID NO: 1 as a 52 bp element when it should have been a 50 bp element or the other way around as Applicants seem to be arguing in their response. The specification clearly states in Example 2 that “a 50 bp growth hormone responsive element” (emphasis added) was used in preparing the expression plasmid and that the SPI-GHRE element is 50 bp in length. See specification at page 3, line 31 where it refers to the “50 bp element named SPI-GHRE” (emphasis added). Attorney argument cannot substitute for evidence. No evidence has been submitted to attest to the use of a 52 bp element rather than a 50 bp element in the working examples. Applicants are invited to submit a declaration to support the proposed amendment to the specification. However, as noted above, Applicant is required to cancel the new matter in reply to this Office Action. Any evidence submitted will be evaluated in view of the proposed amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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New Matter

The rejection of Claims 8-11, 16, 17, 27-30 and 32 under 35 U.S.C. 112, first paragraph, for including new matter in the claims is withdrawn in view of Applicants' amendment to the claims.

Claim 31 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 31 is directed to a DNA according to claim 30, comprising from one to six enhancer elements.

Claim 30 recites the limitation "[a] DNA construct comprising ... at least one enhancer element consisting essentially of the nucleotide sequence TTCTGAGAA." However, Claim 31 covers constructs that comprise enhancer elements other than TTCTGAGAA; only one of the enhancer elements is required to consist essentially of this sequence. The specification does not contemplate DNA constructs that comprise enhancer elements other than those disclosed in the specification, such as other enhancer elements known in the art. Furthermore, the specification does not contemplate using other types of enhancer elements in combination with an enhancer element comprising the nucleotide sequence TTCTGAGAA.

Thus, Claim 31 still includes new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 49 is indefinite in its recitation of "the DNA construct" because the term lacks antecedent basis. Claim 19 now recites a "first DNA construct" and a "second DNA construct."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 27-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon et al. (1990), for reasons of record advanced on pages 5-6 of the Office Action of Paper No. 27 (mailed 8/15/01), as applied to Claims 19, 20, and 49, and in the Office Action of Paper No. 16 (mailed 4/26/00), and in the Office Action of Paper No. 19 (mailed 11/22/00).

Claims 27-32, as amended, define an expression vector anticipated by Yoon et al. (1990). Claim 27 is directed to an expression vector comprising a structural gene encoding a protein, a promoter upstream of and operably linked to the structural gene, and at least one enhancer element consisting essentially of the nucleotide sequence TTCTGAGAA upstream of the promoter. Yoon et al. (1990) discloses such a vector.

At page 12-13 of the response, Applicants argue that Yoon et al. do not teach an expression vector or DNA construct wherein an enhancer element consisting essentially of the nucleotide sequence TTCTGAGAA is incorporated into the expression vector or DNA construct upstream of the promoter. Applicants further argue that the skilled artisan would not expect an enhancer element consisting

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essentially of the nucleotide sequence TTCTGAGAA to incorporate upstream of a promoter as recited in claims 27 and 30. However, this simply is not true.

As discussed in the Office Action of Paper No. 27 (mailed 8/15/01), since the enhancer element is located upstream of the promoter, some spacing between the promoter and the enhancer element is to be expected. The constructs described by Yoon et al. are of this type (i.e., the enhancer element is not directly adjacent to the promoter, rather there are a number of nucleotides that act as spacers between the enhancer and the promoter). Yoon et al. need not teach a segment smaller than the 50 bp segment set forth as SPI-GHRE which is responsive to the growth hormone, because the segment that they used included the nucleotide sequence recited in the claim and the arrangement of genetic elements (i.e., enhancer, promoter, structural gene) is the same as that described in the instant specification. The enhancer element that Yoon et al. used did in fact "consist essentially of" TTCTGAGAA despite the fact that they included some flanking sequences in their constructs as well. It is not necessary that Yoon et al. recognize or teach the minimal sequence that will function as an enhancer, because no matter how long the piece of DNA is initially, once it is incorporated into the DNA construct it necessarily becomes flanked by other nucleotides.

Claims 5, 7, 15, 23-26, and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,814,517 (Seidel et al.).

The claims are directed to an enhancer element consisting essentially of or consisting of the nucleotide sequence TTCTGAGAA.

Seidel et al. disclose SEQ ID NO : 35 which is TTCTCAGAA. This is the complementary strand of the enhancer element. Since the enhancer element is necessarily double-stranded, SEQ ID NO: 35 is 100% identical to the claimed enhancer element.

Thus, the prior art discloses the claimed enhancer element.

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Conclusion

Claims 1, 2, 8-11, 16-17, 19-21, 34-36, 39-42, 44-48, 50, and 52 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, William Phillips, whose telephone number is (703) 305-3388.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER